OCT 2 5 2011

K112842
P 1/4

Section 6 — 510(k) Summary [21 CFR 807.92]

Submitter's Name and Address

Matthew D. Stepanek
Senior Regulatory Affairs Specialist
American Medical Systems, Inc.
952-939-7023 (telephone)
952-930-5785 (fax)
matt.stepanek@ameircanmedicalsystems.com

Alternate Contact Name and Information

Josh Clarin
Regulatory Affairs Manager
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, MN 55343
952-939-7072 (telephone)
952-930-5785 (fax)
josh.clarin@ameircanmedicalsystems.com

Date the Summary was Prepared

September 27, 2011

Device Classification Names

Surgical Mesh, polymeric
Mesh, surgical, gynecologic, for pelvic organ prolapse transvaginally placed

Device Common/Usual Name

Surgical Mesh

Device Trade/Proprietary Name

AMS Elevate PC Anterior and Apical Prolapse Repair System with IntePro Lite
AMS Elevate PC Apical and Posterior Prolapse Repair System with IntePro Lite

K112842
p 2/4

Product Codes

FTL and OTP

Classification of Device

Class II
21 CFR Part 878.3300

Predicate Device(s)

Device Name	Submission Number	Clearance Date
AMS Elevate PC Anterior and Apical Prolapse Repair System with IntePro Lite AMS Elevate PC Apical and Posterior Prolapse Repair System with IntePro Lite	K111118	July 1, 2011

Device Description

The AMS Elevate PC Prolapse Repair Systems with IntePro Lite consist of a permanently-implanted synthetic mesh assembly, non-implantable needle passers, and other surgical aids that are designed to help place the mesh assembly in the pelvic floor.

The devices are identical to the predicate device AMS Elevate PC Prolapse Repair Systems with IntePro Lite, with the following exception of the modification of the Apical Needle Passer Sheath. There are no changes to the mesh design, shape, size, material or Indications for Use.

Existing Indication for Use & Proposed Indication for Use

There are no changes to the existing indications for use. Indications for the predicate and modified devices are as follows:

Elevate PC Anterior & Apical Repair System
The Elevate PC Anterior & Apical Repair System is a surgical mesh kit intended for transvaginal surgical treatment to correct anterior vaginal wall prolapse and vaginal apical prolapse. The kit includes instrumentation for transvaginal placement.

Elevate PC Apical & Posterior Repair System
The Elevate PC Apical & Posterior Repair System is a surgical mesh kit intended for transvaginal surgical treatment to correct posterior vaginal wall prolapse and vaginal apical prolapse. The kit includes instrumentation for transvaginal placement.

K112842
P3/4

Summary of the Technological Characteristics to the Predicate Device(s)

The modifications to the predicate devices are deemed equivalent and there are no changes to the product performance specifications, device indications for use/intended use and/or device functional scientific technology.

The subject devices use the same surgical approach and mesh placement procedures as the predicate devices.

Summary of Non-Clinical Testing

The components of the AMS Elevate PC Anterior and Apical Prolapse Repair Systems with IntePro Lite (Elevate PC Anterior) and AMS Elevate PC Apical and Posterior Prolapse Repair Systems with IntePro Lite (Elevate PC Posterior) have been tested for design verification, biocompatibility, sterilization, and packaging.The test results conclude the subject device to be substantially equivalent to the predicate device.

Substantial Equivalence

The modified Elevate PC Anterior and Elevate PC Posterior devices use the same surgical approach and mesh placement procedures as the predicate device.

The proposed Elevate PC Anterior and Elevate PC Posterior devices have identical indications for use/intended use, identical implant materials, identical sterilization methods; and similar delivery tool materials/characteristics as the predicate.

The proposed Elevate PC Anterior and Elevate PC Posterior device performance and fundamental scientific technology remains unchanged. The differences between the proposed device and the predicate device does not have any negative effect on the safety and effectiveness of the device.

Conclusion

AMS considers the modified Elevate PC Anterior and Elevate PC Posterior devices to be substantially equivalent to the predicate devices.

Manufacturing Facility

American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, MN 55343

Establishment Registration Number: 2183959

Sterilization Facility

Sterigenics US, Inc.
7775 S Quincy St.
Willowbrook, IL 60527

Establishment Registration Number: 1450293

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Matthew D. Stepanek
Senior Regulatory Affairs Specialist
American Medical Systems
10700 Bren Road West
MINNETONKA MN 55343

SEP 28 2012

Re: K112842
Trade/Device Name: AMS Elevate® PC Anterior and Apical Prolapse Repair System with IntePro® Lite
AMS Elevate® PC Apical and Posterior Prolapse Repair System with IntePro® Lite
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTP
Dated: September 28, 2011
Received: September 29, 2011

Dear Mr. Stepanek:

This letter corrects our substantially equivalent letter of October 25, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

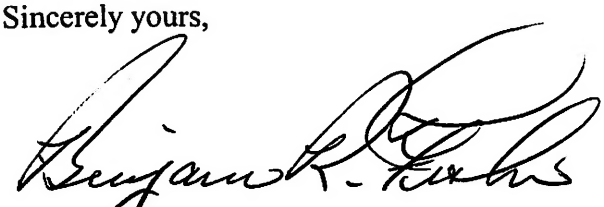
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K112842

Section 5 Statement of Indications for Use

510(k) Number: ~~TBD~~ K112842

Device Name: AMS Elevate® PC Anterior and Apical Prolapse Repair System with IntePro® Lite
AMS Elevate® PC Apical and Posterior Prolapse Repair System with IntePro® Lite

Indications for Use:

AMS Elevate PC Anterior and Apical Prolapse Repair System with IntePro Lite
The Elevate PC Anterior & Apical Repair System is a surgical mesh kit intended for transvaginal surgical treatment to correct anterior vaginal wall prolapse and vaginal apical prolapse. The kit includes instrumentation for transvaginal placement.

AMS Elevate PC Apical and Posterior Prolapse Repair System with IntePro Lite
The Elevate PC Apical & Posterior Repair System is a surgical mesh kit intended for transvaginal surgical treatment to correct posterior vaginal wall prolapse and vaginal apical prolapse. The kit includes instrumentation for transvaginal placement.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-The Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112842